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| APPLICATION NO. FILING DATE    |                 | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |  |
|--------------------------------|-----------------|----------------------|-------------------------|------------------|--|
| 09/913,345                     | 03/25/2002      | Jan Gerrit Garssen   | 5034US                  | 8607             |  |
| 7                              | 7590 01/27/2006 | EXAMINER             |                         |                  |  |
| Trask Britt & Rossa            |                 |                      | SWARTZ, RODNEY P        |                  |  |
| PO Box 2550<br>Salt Lake City. | . UT 84110      | ART UNIT             | PAPER NUMBER            |                  |  |
| <u> </u>                       | , ••••••        |                      | 1645                    |                  |  |
|                                |                 |                      | DATE MAILED: 01/27/2006 |                  |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

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|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|----------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|------------------------------------------------------------------------|--------------|--|--|--|
| Office Action Summary                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                   | 09/913,345                                                                                     | j                                                              | GARSSEN ET AL.                                                                                      |                                                                        |              |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                   | Examiner                                                                                       |                                                                | Art Unit                                                                                            |                                                                        |              |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                   |                                                                                                | Rodney P.                                                      | Swartz, Ph.D.                                                                                       | 1645                                                                   |              |  |  |  |
| The M<br>Period for Reply                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | AILING DATE of this commun                                                                                                                                                                                                                                                                                        | nication appe                                                                                  | ears on the                                                    | cover sheet with the c                                                                              | orrespondence ad                                                       | dress        |  |  |  |
| WHICHEVER - Extensions of tin after SIX (6) MO - If NO period for - Failure to reply we can be compared to the | ED STATUTORY PERIOD F<br>R IS LONGER, FROM THE M<br>ne may be available under the provisions<br>NTHS from the mailing date of this common<br>reply is specified above, the maximum state of the set or extended period for reply<br>ed by the Office later than three months arm adjustment. See 37 CFR 1.704(b). | MAILING DA<br>s of 37 CFR 1.130<br>munication.<br>tatutory period with<br>will, by statute, or | TE OF THI 6(a). In no even ill apply and will cause the applic | S COMMUNICATION t, however, may a reply be time expire SiX (6) MONTHS from ation to become ABANDONE | N.<br>nety filed<br>the mailing date of this α<br>D (35 U.S.C. § 133). |              |  |  |  |
| Status                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                   |                                                                                                |                                                                |                                                                                                     |                                                                        |              |  |  |  |
| 1)⊠ Respor                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | sive to communication(s) file                                                                                                                                                                                                                                                                                     | ed on 8 Nev                                                                                    | ember 200                                                      | 5.                                                                                                  |                                                                        |              |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                   | 2b)⊠ This                                                                                      |                                                                |                                                                                                     |                                                                        |              |  |  |  |
| <u>'</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                   |                                                                                                |                                                                |                                                                                                     |                                                                        |              |  |  |  |
| ,—                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.                                                                                                                                                                                                                 |                                                                                                |                                                                |                                                                                                     |                                                                        |              |  |  |  |
| Disposition of C                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | laims                                                                                                                                                                                                                                                                                                             |                                                                                                |                                                                |                                                                                                     |                                                                        |              |  |  |  |
| 4)⊠ Claim(s                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 4)⊠ Claim(s) <u>1-7,11-16,20 and 21</u> is/are pending in the application.                                                                                                                                                                                                                                        |                                                                                                |                                                                |                                                                                                     |                                                                        |              |  |  |  |
| ·                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 4a) Of the above claim(s) is/are withdrawn from consideration.                                                                                                                                                                                                                                                    |                                                                                                |                                                                |                                                                                                     |                                                                        |              |  |  |  |
| 5) Claim(s                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | is/ o/ the above slaim(s) is/are allowed.                                                                                                                                                                                                                                                                         |                                                                                                |                                                                |                                                                                                     |                                                                        |              |  |  |  |
| 6) Claim(s                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | ∑ Claim(s) <u>1-7,11-13, 15, 16,20,21</u> is/are rejected.                                                                                                                                                                                                                                                        |                                                                                                |                                                                |                                                                                                     |                                                                        |              |  |  |  |
| 7) Claim(s                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | ☑ Claim(s) <u>14</u> is/are objected to.                                                                                                                                                                                                                                                                          |                                                                                                |                                                                |                                                                                                     |                                                                        |              |  |  |  |
| 8)☐ Claim(s                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | s) are subject to restric                                                                                                                                                                                                                                                                                         | ction and/or                                                                                   | election re                                                    | quirement.                                                                                          |                                                                        |              |  |  |  |
| Application Pap                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | ers                                                                                                                                                                                                                                                                                                               |                                                                                                |                                                                |                                                                                                     |                                                                        |              |  |  |  |
| 9)∐ The spe                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | cification is objected to by th                                                                                                                                                                                                                                                                                   | e Examiner                                                                                     | •                                                              |                                                                                                     |                                                                        |              |  |  |  |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                   |                                                                                                |                                                                |                                                                                                     |                                                                        |              |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                   |                                                                                                |                                                                |                                                                                                     |                                                                        |              |  |  |  |
| Replace                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | ment drawing sheet(s) including                                                                                                                                                                                                                                                                                   | g the correction                                                                               | on is require                                                  | d if the drawing(s) is obj                                                                          | jected to. See 37 CF                                                   | FR 1.121(d). |  |  |  |
| 11)∐ The oat                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | h or declaration is objected to                                                                                                                                                                                                                                                                                   | o by the Exa                                                                                   | aminer. Not                                                    | e the attached Office                                                                               | Action or form P7                                                      | O-152.       |  |  |  |
| Priority under 3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 5 U.S.C. § 119                                                                                                                                                                                                                                                                                                    |                                                                                                |                                                                |                                                                                                     |                                                                        |              |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of: <ol> <li>Certified copies of the priority documents have been received.</li> <li>Certified copies of the priority documents have been received in Application No</li> <li>Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> </ol> </li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                   |                                                                                                |                                                                |                                                                                                     |                                                                        |              |  |  |  |
| 2) D Notice of Drafts                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | ences Cited (PTO-892) sperson's Patent Drawing Review (F closure Statement(s) (PTO-1449 or ail Date                                                                                                                                                                                                               |                                                                                                | !                                                              | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:                          | ate                                                                    | D-152)       |  |  |  |

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### **DETAILED ACTION**

### **Continued Examination Under 37 CFR 1.114**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8 November 2005 has been entered.

Claims 10, 18, and 19 have been canceled. Claims 1, 13, and 14 have been amended.

New claims 20 and 21 have been added.

2. Claims 1-7, 11-16, 20 and 21 are pending and under consideration.

# **Rejections Moot/Withdrawn**

- 3. The rejection of claim 10 under 35 U.S.C. 112, second paragraph, indefiniteness, is moot in light of the cancelation of the claim.
- 4. The rejection of claim 19 under 35 U.S.C. 112, second paragraph, indefiniteness, is moot in light of the cancelation of the claim.
- 5. The rejection of claims 18 and 19 under 35 U.S.C. 103(a) as being unpatentable over Bell et al (*Neuropathology and Applied Neurobiology*, 23(1)26-35, 1997) is moot in light of the cancelation of the claims.
- 6. The rejection of claim 10 under 35 U.S.C. 102(b) as being anticipated by Grathwohl et al (*Journal of Virological Methods*, <u>64</u>:205-216, 1997) is moot in light of the cancelation of the claim.

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7. The rejection of claims 18 and 19 under 35 U.S.C. 103(a) as being unpatentable over Grathwohl et al (*Journal of Virological Methods*, <u>64</u>:205-216, 1997) is moot in light of the cancelation of the claims.

8. The rejection of claims 13 and 14 under 35 U.S.C. 112, second paragraph, indefiniteness, is withdrawn in light of the amendment of the claims.

# **Rejections Maintained**

9. The rejection of claims 1-5, 11-13, and 15 and now new claim 21 under 35 U.S.C. 102(b) as being anticipated by Grathwohl et al (*Journal of Virological Methods*, <u>64</u>:205-216, 1997) is maintained.

Applicants' argue that the cited reference does not anticipate the instant claims because sample preparation of the instant claims is different from that taught by Grathwohl et al.

Applicants' arguments are not found persuasive because of the open language of the instant claims, i.e., a method "comprising" the listed steps. The use of the open language encompasses not only the listed steps, but may also comprise unlisted steps. In addition, one of the embodiments is preparation by a "functional equivalent" of guanidine thiocyanate. The term, while mentioned in the specification, is not defined. Therefore, the examiner considers "functional equivalent" to include proteinase K. Thus, the methods of Grathwohl et al do read on the instant claims because of the open language of the claims as well as the use of a "functional equivalent".

New claim 21 is included in this rejection because if the claim had been originally submitted with the other claims, claim 21 would have been rejected for the same reasoning.

10. The rejection of claims 6 and 7 under 35 U.S.C. 103(a) as being unpatentable over Grathwohl et al (*Journal of Virological Methods*, <u>64</u>:205-216, 1997) is maintained.

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Applicants' argue that it would not have been obvious to utilize the methods of Grathwohl et al because sample preparation of the instant claims is different from that taught by Grathwohl et al.

The examiner has considered applicants' argument, but does not find it persuasive for the reasons discussed *supra*, and the reasoning put forth in the original rejection.

## Claim Rejections - 35 USC § 112

- 11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

  The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 12. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 preamble recites obtaining at least one sample from "a" mammal, indicating that the samples do not come from multiple mammals. However, the fourth step recites test "subjects", presumably indicating multiple mammals. Clarification is required to resolve the number of "mammal subjects".

13. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 depends from a rejected claim.

#### **Conclusion**

- 14. No claims are allowed.
- 15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571)

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272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RODNEY P SWARTZ, PH.D PRIMARY EXAMINER Art Unit 1645

January 23, 2006